



DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2023-0041]

Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillator (ICD)

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of denials.

SUMMARY: FMCSA announces its decision to deny the applications from four individuals treated with an Implantable Cardioverter Defibrillator (ICD) who requested an exemption from the Federal Motor Carrier Safety Regulations (FMCSRs) prohibiting operation of a commercial motor vehicle (CMV) in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope (transient loss of consciousness), dyspnea (shortness of breath), collapse, or congestive heart failure.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue, SE, Room W64-224, Washington, DC 20590-0001, (202) 366-4001, fmcsamedical@dot.gov. Office hours are from 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing materials in the docket, contact Dockets Operations, (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Comments

To view comments go to www.regulations.gov. Insert the docket number (FMCSA-2023-0041) in the keyword box and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, and click “Browse Comments.” If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366-9317 or (202) 366-9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption requests. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov. As described in the system of records notice DOT/ALL 14 (Federal Docket Management System), which can be reviewed at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>, the comments are searchable by the name of the submitter.

II. Background

On February 13, 2023, FMCSA published a notice announcing receipt of applications from four individuals treated with ICDs and requested comments from the public (88 FR 9318). The individuals requested an exemption from 49 CFR 391.41(b)(4) which prohibits operation of a CMV in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive heart failure. The public comment period ended on March 15, 2023, and one comment was received.

FMCSA has evaluated the eligibility of the applicants and concluded that granting an exemption would not provide a level of safety that would be equivalent to, or greater

than, the level of safety that would be obtained by complying with § 391.41(b)(4). A summary of each applicant's medical history related to their ICD exemption request was discussed in the February 13, 2023, *Federal Register* notice (88 FR 9318), and will not be repeated here.

The Agency's decision regarding this exemption application is based on information from the Cardiovascular Medical Advisory Criteria, an April 2007 evidence report titled "Cardiovascular Disease and Commercial Motor Vehicle Driver Safety,"¹ and a December 2014 focused research report titled "Implantable Cardioverter Defibrillators and the Impact of a Shock in a Patient When Deployed." Copies of these reports are included in the docket.

FMCSA has published advisory criteria to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.² The advisory criteria for § 391.41(b)(4) indicates that coronary artery bypass surgery and pacemaker implantation are remedial procedures and thus, not medically disqualifying. ICDs are disqualifying due to risk of syncope.

III. Discussion of Comments

FMCSA received one comment in this proceeding. The comment was from a cardiovascular specialty nurse. The commenter indicated that a review of the applicant's "clinical presentation and health status" is more important to consider rather than just the physical presence of an ICD, suggesting that a decision on whether to grant an exemption should be made on an individualized basis considering those factors.

As stated in this notice in the section below, FMCSA evaluates each exemption application on an individualized basis considering all medical information to include

¹ The report is available on the internet at <https://rosap.ntl.bts.gov/view/dot/16462>.

² These criteria may be found in 49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section D. *Cardiovascular: § 391.41(b)(4)*, paragraph 4, which is available on the internet at <https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf>.

what is provided by the applicant, available medical and scientific data concerning ICDs, and any relevant public comments received. Not only does FMCSA consider the physical presence of an ICD, but also the underlying condition for which the ICD was implanted that places the individual at high risk for loss of ability to operate a CMV.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.

The Agency's decision regarding these exemption applications is based on an individualized assessment of the applicants' medical information, available medical and scientific data concerning ICDs, and any relevant public comments received.

In the case of persons with ICDs, the underlying condition for which the ICD was implanted places the individual at high risk for syncope or other unpredictable events known to result in gradual or sudden incapacitation. ICDs may discharge, which could result in loss of ability to safely control a CMV. The December 2014 focused research report referenced previously upholds the findings of the April 2007 report and indicates that the available scientific data on persons with ICDs and CMV driving does not support that persons with ICDs who operate CMVs are able to meet an equal or greater level of safety.

V. Conclusion

The Agency has determined that the available medical and scientific literature and research provides insufficient data to enable the Agency to conclude that granting these exemptions would achieve a level of safety equivalent to, or greater than, the level of safety maintained without the exemption. Therefore, the following applicants have been denied an exemption from the physical qualification standards in § 391.41(b)(4):

Kevin Coughlin (MA)	Charles Halepakis (MA)
Antonio Maceroni (MI)	Michael Wilson (FL)

The applicants have, prior to this notice, received a letter of final disposition regarding their exemption request. The decision letter fully outlined the basis for the denial and constitute final action by the Agency. The names of these individuals published today summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4).

Larry W. Minor,
Associate Administrator for Policy.

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